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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/494,212	01/25/2000	Shi-Lung Lin	USP9768A-EI	3155

7590 12/18/2002  
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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 12/18/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/494,212

Applicant(s)

LIN ET AL.

Examiner

Bradley L. Sisson

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1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,7-18,20,25,26 and 29-35 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 1-3,7-18,20,25,26 and 29-35 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1-3, 7-18, 20, 25, 26, and 29-35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mallet et al. (US Patent 5,817,465) in view of Van Gelder et al.
4. Mallet et al., disclose a method whereby mRNA is amplified. As seen in column 5, the method can entail the use of a primer that can contain in the 5' region, a non-specific oligonucleotide tail that can contain a promoter region. In column 6, bridging to column 7, Mallet et al., disclose performing reverse transcription on the RNA so to produce a cDNA. The cDNA is then subjected to amplification using a second primer. Column 6, lines 51-58, disclose suitable reverse transcriptases. This meets a limitation of claim 7.

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5. The aspect of performing one or more rounds of amplification are disclosed at column 7, last paragraph.
6. The aspect of using mRNA as a starting material is disclosed at column 9, last paragraph; see also column 16.
7. Mallet et al., do not teach using a first primer that contains an oligodeoxythymidylate region nor do they disclose synthesizing RNA from the cDNA amplicons.
8. Van Gelder et al., page 1663, disclose a method whereby mRNA is subjected to reverse transcription and is then primed with a first primer that contains an oligodeoxythymidylate region as well as a promoter for an RNA polymerase. Page 1664, left column, discloses performing transcription of the amplified cDNA with an RNA polymerase.
9. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Mallet et al., with the method of Van Gelder et al., whereby the first primer of Van Gelder et al., was substituted into the method of Mallet et al., as Mallet et al., in as much teaches the use of a variety of primers, including primers that contain tails and promoter regions. It would have also been obvious to said ordinary artisan to have incorporated the steps of synthesizing RNA copies from the cDNA amplicons as Van Geller et al., teaches explicitly of using an RNA polymerase so to effect transcription and Mallet teaches using first primers that contain promoter regions that could then be used in conjunction with such a polymerase. In view of the detailed guidance, reproducibility in the art, and explicit guidance, the ordinary artisan would have been highly motivated to produce such a method and would have had a most reasonable expectation of success.

Response to arguments

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10. At page 4 of the response received 26 September 2002, argument is advanced that "the resulting RNA of Van Gelder's method is antisense RNA (aRNA) which is complementary to original mRNA and cannot be translated into protein."

11. The above argument has been fully considered and has not been found to be persuasive towards the withdrawal of the rejection. While agreement is reached in that antisense RNA is generated by the method of Van Gelder, it is noted with particularity that the present method places no restriction upon which strand of the cDNA is being amplified. It is noted that the present claims have not been found to contain any limitation that the amplified RNA be capable of translation into a protein. Accordingly, applicant is arguing limitations not present in the claims.

12. At page 5, paragraph 8, of the response, it is asserted, "Mallet et al. do not use sense RNA...." This argument has not been found to be persuasive for as shown above, Mallet et al., teach explicitly of using just such a starting material; see columns 15 and 16 of the patent.

For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

#### ***Conclusion***

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

14. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

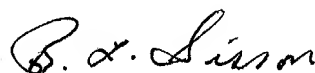
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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

17. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

BLS  
December 16, 2002